Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 2953348

July 2, 2002

Joseph F. Rynewicz, Owner
Far West Marine
P.O. Box 4701
San Jose, CA 95150-4701

WARNING LETTER

On March 21 and 22, 2002, we inspected your seafood processing facility, located at 493 Lake Avenue, Santa Cruz, California. We found that you have serious deviations from the seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your scombroid species fish (tuna, mahi, escolar, and ono) to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You may find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov. We have enclosed a handout, which gives information on how to obtain the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001.

Your serious HACCP deviations are as follows:

1. You must have a HACCP plan that lists the critical limits that must be met at each of the critical control points, to comply with 21 CFR 123.6(c)(3). However,

   a. Your firm's HACCP plan for fresh tuna, mahi, ono, escolar, and Yellowtail, lists critical limits as primary processor of [redacted]°F for day boat delivery and [redacted]°F for multiple day boat delivery at the receiving critical control point that are not adequate to control histamine formation. FDA suggests that other preventative measures be used in conjunction with monitoring internal temperatures, such as sensory examinations and harvest vessel records.

      Chapter 7 of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition can help you determine the best combination of procedures for your process. We have enclosed a copy of Chapter 7 for your ready reference.

We note that your monitoring procedures include "Boat Process Records." If you choose to require these records upon receipt of the fish, you should include this as part of your critical limits.

b. Your firm's HACCP plan for fresh tuna, mahi, ono, escolar, and Yellowtail fails to list a critical limit for the scombroid fish you receive as a secondary processor.

For secondary processors of scombroid fish delivered refrigerated (not frozen), FDA recommends that either:

All lots received are accompanied by transportation records (e.g., temperature recording chart) that show the fish were held at or below 40°F throughout transit

OR

For fish held under ice or other cooling media at the time of delivery--there is an adequate quantity of ice or other cooling media to completely surround the product.

OR

For fish delivered with a total transit time of 4 hours or less, the internal temperature of a representative number of fish in the lot at the time of delivery is not more than 40°F.

2. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be adequate and appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for fresh tuna, mahi, ono, escolar, and Yellowtail at the storage critical control point is not adequate. Your corrective action plan addresses the cause of the temperature deviation but does not address the corrective action to be taken with the product.

3. You must have sanitation control records that, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records. These records must address the following:

- Safety of water
- Condition and cleanliness of food-contact surfaces
- Prevention of cross-contamination
- Maintenance of hand-washing, hand-sanitizing, and toilet facilities
- Protection from adulterants
- Labeling, storage, and use of toxic compounds
- Employee health conditions
- Exclusion of pests

In your letter of April 7, 2002, you have attached a copy of your Sanitation Standard Operating Procedure. The Sanitation Standard Operating Procedure does not, however, include all of the above elements. Please note that you must maintain monitoring and corrective action records of sanitation controls.

4. You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish or fishery product you process, and you must have a HACCP plan that lists these food safety hazards, to comply with 21 CFR 123.6(a) and 123.6(c)(1). However, your firm's HACCP plan for Yellowtail does not list the food safety hazard of Ciguatera fish poison.

5. You must have a HACCP plan that lists the monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for fresh tuna, mahi, ono, escolar, and Yellowtail, lists a monitoring frequency at the storage critical control point that is not adequate to control the hazards listed in your HACCP plan for histamine-producing species.

Your firm receives and processes several histamine-producing species and a Ciguatera fish poison-producing species. Chapter 7 of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001, can help you determine the most appropriate methods for controlling the hazards associated with histamine-producing species of fish. Chapter 6 can help you with the most appropriate methods for controlling the hazards associated with Ciguatera fish poison species of fish. As mentioned above, see attached handout on how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations. Please note that FDA inspection addressed your scombroid fish processing only. Accordingly, we have not commented on your HACCP plans for salmon and shellfish.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. It has been more than three months since FDA inspection. We acknowledge receipt of your letter of April 7, 2002 responding to the Form FDA 483 issued to you at the close of the inspection. Please provide this office with information on what progress you have made in achieving FDA compliance with the seafood HACCP regulations. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District

Enclosures:

Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition
Copy of Chapter 7 of Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition
Form FDA 483